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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,553

02/24/2005

M.V. Ramana Reddy

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DRINKER BIDDLE & REATH  
ATTN: INTELLECTUAL PROPERTY GROUP  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

EXAMINER

KUMAR, SHAILENDRA

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

09/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/525,553

Applicant(s)

REDDY ET AL.

Examiner

SHAIENDRA -. KUMAR

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 8, 11, 15, 16, 18, 19, 21, 23, 26-34, 37, 42, 53, 83 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 22, 35, 43, 45-47, 50, 52, 54, 56, 60, 62, 68, 70, 76, 77, 84-89 and 91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,8,11,15,16,18,19,21-35,37,42,43,45-47,50,52-54,56,60,62,68,70,76,77 and 83-91.

### **DETAILED ACTION**

This office action is in response to applicants' communication filed on 6/18/07.

Original claims 1-2, 8, 11, 15-16, 18-19, 21-35, 37, 42-43, 45-47, 50, 52-54, 56, 60, 62, 68, 70, 76-77, 83-89 and newly added claims 90-91 are pending in this application.

Claims 3-7, 9-10, 12-14, 17, 20, 36, 38-41, 44, 48-49, 51, 55, 57-59, 61, 63-67, 69, 71-75 and 78-82 have been canceled.

Claims 8, 11, 15-16, 18-19, 21, 23, 26-34, 37, 42, 53, 83 and 90 have been withdrawn from the consideration, being drawn to the non elected invention.

Applicants correctly point out that claim 8 was inadvertently included in the examination.

Claim 8 is in fact withdrawn from the consideration being drawn to the non elected invention. With respect to claim 60, applicants are correct that claim 60 was indeed shown as rejected and no ground of rejection was given. The error is regretted. Claim 60 was under consideration.

Furthermore, claims 24 and 25 were indeed examined, and were inadvertently included as withdrawn claims in the PTO form 327. The error is regretted.

Thus claims 1-2, 22, 24-25, 35, 43, 45-47, 50, 52, 54, 56, 60, 62, 68, 70, 76-77 and 84-89 and 91 are under examination.

Applicants' request for reconsideration of restriction requirement was considered and not found convincing. Applicants point out to the PCT and WIPO requirement and suggest that the same requirement should be applied in herein. The examiner agrees that the instant application is a 371 application, however, there are certain US practices that is different than PCT practices, especially in view of the fact that compounds are

large Markush group. With respect to Group III invention, which are conjugates, they are divergent subject matter and classified separately.

***Claim Objections***

1. Claims 54, 56, 60, 86, 87-89 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend from claim 1, and claim neither describes radioactive compound, nor cytoprotective compound. Claim 1 simply describes compound, whereas, above claims are describing radioactive compound or cytoprotective compounds.

***Claim Rejections - 35 USC § 112***

2. Claims 43, 45-47, 50, 52, 54, 56,60, 62, 68, 70, 76-77 and 84-89 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As pointed out in the office action of 4/13/07 these claims fail to comply with the In re Wands factor.

Applicants' argument were fully considered and were not found convincing. Applicants argue that they the presumption with respect to how to make and use the invention. Examiner disagrees. Applicants have made some compounds, but have failed with respect to as to how to use these compounds. Applicants point out that researchers have identified the cell cycles as being crucial in diseases involving

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abnormal cell proliferation, and thus anti cancer drugs are available and each drug is effective versus range of cancers, and gives the example of cis-platin. At the out set, instant claimed compounds are nowhere near cis-platin with respect the structure. Since, cis-platin is well known drug for various cancer, does not lead to believe, that instant claimed compounds will behave the same way as the cis-platin. Cis-platin is well-established drug, which have been rigorously tested in the clinical studies and applicants' comparison of its compounds to cis-platin is without any merit.

Applicants also admit on page 8 of their response that treatment of cancer is unpredictable. Applicants also point out that broadly useful anticancer drugs are available for treatments. The examiner does not dispute the statement, but none of the treatments include structurally similar compounds as claimed in herein.

Applicants have also pointed out to various references to show that in-vitro screening methods are available and later on they end up in in-vivo studies. Again, none of these references suggest compounds, which are structurally similar to those, claimed in herein. Applicants argue that ample guidance and working examples are provided in herein. Just citing NCI data does not give weightage to applicants' data, absent evidence to the contrary. Applicants' assumption that in-vitro data is indicative of in-vivo test is not always true. If it were true, cancer will not exist today.

Applicants in Table 5(page 100-101) present data for some compounds, out of million compounds that can be made out of generic claim in herein. What kid of statistical analysis can be drawn out of the test? Some of the compounds were not

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even tested. Applicants even admit that activity is not consistent across different diseases, see page 60 of the response.

Applicants point out that they agree that there is no “absolute predictability” and concedes that not every compound within the scope of the invention will be useful. Applicants should limit to the scope of the compounds that are effective against some cell lines.

The examiner disagrees with the undue experimentation part of the arguments. In view of the large myriads of the compounds claimed for treating every type of cancers, is indeed part of undue experimentation.

***Claim Rejections - 35 USC § 103***

3. Claims 1-2, 22, 35 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamori et al (JP 2001-139550).

Applicants argue that there should be some suggestion and reasonable expectation that the reference renders instant claims prima facie obvious. The suggestion and reasonable expectation comes from the fact the reference teaches structurally similar compounds and composition. Applicants point out that the abstract of the reference demonstrates enormous diversity of the compounds. The examiner believes, that instant claimed compounds are as broad and diversified as the reference compounds. The examiner has very clearly stated as to why the instant claimed compounds would be obvious over prior art of record. Applicants arguments with respect to the use of the compound is of little if any probative value inasmuch as compounds and composition per se are prima facie obvious. Applicants point out to

some essential features of the reference. The examiner would like to point out that the reference should be read in its entirety as to what it teaches. Applicants point out to examiner's comment on equivalence of OH and methoxy. Inasmuch the reference have made compounds having OH and OMe substituents, they are indeed equivalent.

Applicants question that the examiner has not pointed out to any compound in claim 22, which is taught by the reference. The examiner would like to point that there is no 35 USC 102 issue here. Inasmuch as the substituents are similar, compounds are structurally similar, one of ordinary skill in the art would be motivated to make those compounds.

4. Claims 24-25 are again rejected under 35 U.S.C. 103(a) as being unpatentable over US'521, for the reasons of record as set forth in the office action of 4/13/07.

Instant claims are directed to process of making compounds, which are similar to those claimed in herein, see Fig 15, Fig 16 and Fig 25.

Applicants argue that the examiner is making same error, which was made by an examiner in re Ochiai. The examiner disagrees. In re Ochiai suggests that if compounds are patentable, process of making the compounds is patentable. In the present case, instant compounds have not been found patentable yet.

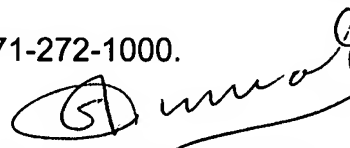
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SHAIENDRA - KUMAR  
Primary Examiner  
Art Unit 1621

S.Kumar  
8/31/07